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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,424	07/23/2003	Tiecheng A. Qiao	85504D-W	9183

7590 04/06/2007  
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EXAMINER
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HYUN, PAUL SANG HWA

ART UNIT	PAPER NUMBER
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1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/625,424	QIAO ET AL.	
	Examiner	Art Unit	
	Paul S. Hyun	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### REMARKS

Claims 1-19 are currently pending. Claims 18 and 19 remain withdrawn.

Applicants did not amend the claims. Despite Applicants' arguments, the prior art rejections cited in the previous Office action are maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **1-5, 7-12 and 14-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. (US 6,429,027 B1) in view of Leblans et al. (US 2004/0069857 A1).

Chee et al. disclose a two-dimensional array of microspheres randomly immobilized in wells of a substrate (see Figs. 1A, 1B and line 2, col. 5), wherein the concentration of the microspheres can range from a single microsphere to 2 billion

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microspheres per  $\text{cm}^2$  (see lines 1-33, col. 6). The size of the microspheres can range between 0.2 to 200 microns (see lines 33-40, col. 9). The microspheres bear biological probes in the form of a bioactive agent (i.e. nucleic acids [see claim 12]) that binds an analyte of interest (see claim 1). The microspheres can comprise a dye in the form of chromophores that can be developed to produce a unique optical signature that allows one to visually identify the microspheres and the bioactive agent bound to the microspheres (see claim 5 and line 25, col. 21). Chromophores as defined by the Specification absorb light and convert the absorbed light into heat, which is a photo initiated process (see lines 8-10, col. 2).

The microspheres disclosed by Chee et al. differ from the claimed invention in that the reference does not disclose that the dye is a colorless dye that can be developed to a colored state.

Leblans et al. disclose photochromic dyes for identifying microspheres (see [0056]). The disclosed photochromic dyes are colorless and undergo an irreversible change in light absorption in the presence of specific wavelengths of electromagnetic radiation. The reference discloses that the photochromic dyes are advantageous because the color change is irreversible.

It would have been obvious to one of ordinary skill in the art to use the photochromic dyes disclosed by Leblans et al. to identify the microspheres disclosed by Chee et al. since the photochromic dyes disclosed by Leblans et al. undergo permanent color change.

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Claim **13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. in view of Leblans et al. as applied to claims 1-5, 7-12, 14-17, and further in view of Wang (US 4,663,277).

Neither Chee et al. nor Leblans et al. disclose the immobilization of the microspheres by a gelation process.

Wang discloses an immunoassay for a virus accomplished by utilizing microspheres coated with antiviral antibodies. The reference discloses that the method of the immunoassay involves immobilizing the microspheres by placing the microspheres in a gel (see lines 46-50 col. 9).

It would have been obvious to one of ordinary skill in the art to further immobilize the modified microspheres disclosed by Chee et al. and Leblans et al. by means of a gel as taught by Wang so that the microspheres are better secured within the wells of the substrate.

Claims **1, 3, 5 and 6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. in view of Litt (US 4,092,408).

Chee et al. disclose a two-dimensional array of microspheres randomly immobilized in wells of a substrate (see Figs. 1A, 1B and line 2, col. 5), wherein the concentration of the microspheres can range from a single microsphere to 2 billion microspheres per  $\text{cm}^2$  (see lines 1-33, col. 6). The size of the microspheres can range between 0.2 to 200 microns (see lines 33-40, col. 9). The microspheres bear biological probes in the form of a bioactive agent (i.e. nucleic acids [see claim 12]) that binds an

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analyte of interest (see claim 1). The microspheres can comprise a dye in the form of chromophores that can be developed to produce a unique optical signature that allows one to visually identify the microspheres and the bioactive agent bound to the microspheres (see claim 5 and line 25, col. 21).

The microspheres disclosed by Chee et al. differ from the claimed invention in that the reference does not disclose that the dye is a colorless dye that can be developed to a colored state.

Litt discloses an enzyme label that interacts with colorless o-nitrophenol dyed sugar to produce a measurable color intensity (see lines 45-55, col. 7). The enzyme cleaves the sugar from the dye and releases the dye. The intensity of the color is proportional to the enzyme activity.

It would have been obvious to one of ordinary skill in the art to provide the microspheres disclosed by Chee et al. with the dye label disclosed by Litt since the label disclosed by Litt allows the quantification of enzyme activity directly from the intensity of the color produced by the enzyme reaction.

### ***Response to Arguments***

Applicants' arguments have been fully considered but they are not persuasive.

In general, it should be noted that the differences in the intended purpose or usage between the claimed invention and the cited references do not affect the applicability of the references as prior art for the purpose of 35 U.S.C. 103(a) rejections. That said, Applicants' arguments will be addressed.

1) Applicants' argument that neither Chee et al. nor Leblans et al. disclose a colorless non-fluorescent latent colorant is not persuasive. As indicated in the rejection, [0056] of the Leblans et al. reference discloses the use of colorless photochromic dyes that irreversibly develop into a color once they're developed (see line 23 of the paragraph). The rejection of claim 13 is sustained for the same foregoing reason.

2) Applicants' argument that Litt does not disclose a non-fluorescent label is not persuasive. Contrary to Applicants' assertion, the enzyme label disclosed by Litt is not fluorescent. The passage of the reference cited by Applicants is directed towards a fluorescent label, not the enzyme label relied upon in the rejection. The reference explicitly distinguishes the fluorescent label from the enzyme label (see lines 45-55, col. 7). Applicant's argument that the combination of Chee et al. and Litt is inoperable is also unpersuasive. Applicants argue that the enzyme label disclosed by Litt would not enable the identification of individual microspheres in the array disclosed by Chee et al. First, it is unclear why the dye disclosed by Litt must cover the entire microarray, as asserted by Applicants. Second, the assay disclosed by Chee et al. does not require an array format (see lines 27-30, col. 6). Rather the assay can comprise a single bioactive agent. Therefore, in the instance that a single bioactive reagent is utilized, the ability to distinctly identify individual microspheres is not required.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

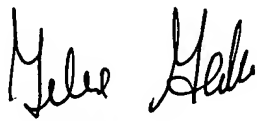
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH  
4/3/07

  
YELENA GAKH  
PRIMARY EXAMINER